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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/824,447	04/02/2001	Tetsuya Ikemoto	210485	9485

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LEYDIG VOIT & MAYER, LTD  
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EXAMINER

AULAKH, CHARANJIT

ART UNIT PAPER NUMBER

1625

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/824,447

Applicant(s)

IKEMOTO ET AL.

Examiner

Charanjit S. Aulakh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. According to paper filed on July 12, 2004, the applicants have canceled claims 1-20 and furthermore, have added new claims 21-37.
2. Claims 21-37 are now pending in the application.

### ***Response to Arguments***

3. Applicant's arguments filed on July 12, 2004 have been fully considered but they are not persuasive. The examiner does not agree with the applicants arguments that the method of Bogeso is similar to the methods of instant reference example 1 and comparative example 1 and therefore, crystals obtained by Bogeso would be expected to have an aspect ratio of approximately 1. The method of crystallization of citalopram hydrobromide described by Bogeso is not closely related to the instant reference example 1 and comparative example 1 but is quite similar to the instant method. The applicants argue that the instant reference example 1 is similar to the first crystallization described by Bogeso ( see col. 5, lines 7-38 ) and the instant comparative example 1 is similar to third crystallization described by Bogeso ( see col. 5, lines 48-54 ). The examiner does not agree with the applicants arguments since these two methods are very different. In the instant reference example 1, citalopram base is dissolved in acetone and then hydrobromic acid gas is blown in to make the pH of solution 3. In this reference example, the crystals begin to precipitate when half of the hydrobromic acid gas was blown in. In contrast, the method of Bogeso teaches that pH is adjusted to 7 by adding some acetone solution and then the mixture is left overnight for

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crystallization. Furthermore, there is no mention of adding seed crystals in the reference example 1 in contrast to the method of Bogeso. Similarly, the comparative example 1 of instant application uses methanol for dissolving citalopram hydrobromide synthesized in reference example 1, charcoal is added and then filtered off before adding isopropyl alcohol and again heated to 58 degree to dissolve the crystals. In contrast to this comparative example 1, the method of Bogeso uses mixture of methanol and acetone and then filtered with charcoal. In view of these different methods for crystallization of citalopram hydrobromide by Bogeso and the instant reference example 1 and comparative example 1, one skilled in the art would not expect that the crystals obtained by Bogeso will have same aspect ratio as obtained by the instant reference example 1. Also, the examiner does not agree with the applicants arguments that in Bogeso's reference, the crystals start to precipitate out of solution after being cooled to 20 degree. Bogeso teaches that the mixture in all three crystallization steps is left overnight for crystallization. Thus, the applicants need to show beneficial effects of controlling the cooling rate on the size of crystals compared to the crystals obtained by Bogeso and furthermore, unexpected result of superior activity of the crystals obtained by the instant process over the crystals obtained by Bogeso since the utility of citalopram hydrobromide as an antidepressant is well known in the prior art.

### ***Conclusion***

4. rejection of claims 21-37 under 35 U.S.C. 103(a) is maintained for the reasons of record.

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**5. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

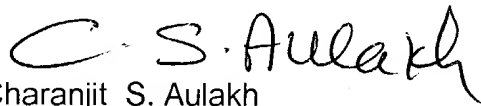
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

**6.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Charanjit S. Aulakh  
Primary Examiner  
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